OSYPKA

OSYPKA AG
Earl-H.-Wood-Str. 1
79618 Rheinfelden
Germany

2.2 Instructions for Use

Version 1.0

Name of Project:

iConnect Catheter Cable

Project Number:

5354

History of Changes

Former Versions

Version No.	Author	Date	Approval
n/a	n/a	n/a	n/a

Changes related to last approved version

Related topic	Kind of change	Reason for change
n/a	n/a	n/a

Approval

	Function	Name	Company	Date	Signature
Author	PM		OSYPKA AG	27.12.22	
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OEM customer	PM		Stereotaxis	09.01.23	

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CE 2797

Conformité Européenne (European Conformity), MDR 2017/745
Conformité Européenne (European Conformity)
European Conformity (Conformité Européenne)

Conformité Européenne (Conformità europea)
Conformité Européenne (conformidad europea)
Conformité Européenne (Europæisk overensstemmelse)
European Compliance (Eurooppalainen vaatimustenmukaisuus)
European conformity (Ευρωπαϊκή συμμόρφωση)
European conformity (Atbilstība Eiropas standartiem)
European conformity (Europese conformiteit)
European conformity (Zgodność europejska)European
conformity (Conformidade Europeia)
Conformité Européenne (i överensstämmelse med EU-direktiv)
Conformité Européenne (zhoda s požiadavkami EU)
Conformité Européenne (Evropska skladnost)
European conformity (evropská konformita)
European conformity (Avrupa Uyumluluğu)European
conformity (Európai megfelelőség)

UKCA 0086

United Kingdom Conformity Assessed

UKRP

United Kingdom Responsible Person:
Dot Medical Ltd. trading at Silk Point
Queens Avenue, Macclesfield, SK10 2BB, United Kingdom

OSYPKA

OSYPKA AG
Earl-H.-Wood-Str. 1, 79618 Rheinfelden, Germany
Tel. +49(0)76237405-0,Fax +49(0)76237405-213
E-mail: mail@osypka.de, Internet: www.osypka.de

STEREOTAXIS

Stereotaxis
4320 Forest Park Avenue, Suite 100
St. Louis, MO 63101, USA
1-866-646-2346
1-314-678-6100

Version: 2022-11-17

YM06221117B_iConnect_Catheter_MDR
9Z-28-0226-A-01

Symbol		Symbol	
⌂ (Date of manufacture)	en o Date of manufacture de o Herstellungsdatum fr o Date de fabrication it o Data di costruzione es o Fecha de fabricación da o Fremstillingsdato fi o Valmistuspäivämäärä nl o Datum van vervaardiging no o Produksjonsdato pt o Data de fabrico sv o Tillverkningsdatum	STERILE EO	en o Sterilisation with ethylene oxide de o Sterilisation mit Ethylenoxid fr o Stérilisation à l'oxyde d'éthylène it o Sterilizzazione con etilenossido es o Esterilización con etilenoxido da • Sterilisering med etylenoxid fi • Sterilointi etyleenoksidilla nl o Sterilisatie met Ethylenoxid no o Sterilisering med etylenoksid pt o Esterilização com Etilenoxid sv o Sterilisering med etylenoxid
▲▲▲ (Manufacturer)	en o Manufacturer de o Hersteller fr o Fabricant it o Produttore es o Fabricante da o Producent fi o Valmistaja nl o Fabrikant no o Produsent pt o Fabricante sv o Tillverkare	📖i	en o Consult Instructions for Use de o Gebrauchsanweisung beachten fr o Consulter les Instructions d'utilisation it o Consultare le Istruzioni per l'uso es o Consultar las Instrucciones de uso da o Se brugsanvisningen fi o Lue käyttöohjeet nl o Raadpleeg de gebruiksinstructies no o Se bruksanvisningen pt o Consultar as Instruções de Utilização sv o Läs bruksanvisningarna
LOT	en o Batch name de o Chargenbezeichnung fr o Nom du lot it o Nome del lotto es o Nombre de lote da o Batchnavn fi o Erän nimi nl o Naam van de partij no o Batchnavn pt o Nome do lote sv o Partiets namn	REF	en o Order number de o Bestellnummer fr o Numéro de commande it o Numero d'ordine es o Número de pedido da o Ordrenummer fi o Tilausnumero nl o Bestelnummer no o Ordrenummer pt o Número de encomenda sv o Ordernummer
⧖ (To be used before)	en o To be used before de o Verwendbar bis fr o À utiliser avant it o Da utilizzare prima del es o Usar antes del da o Bruges inden fi o Viimeinen käyttöpäivä nl o Te gebruiken vóór no o Brukes innen pt o Utilizar antes de sv o Utgångsdatum	⊘ (Do not use if package damaged)	en o Do not use if package damaged de o Nicht verwenden, wenn die Verpackung beschädigt ist fr o Ne pas utiliser si l'emballage est endommagé it o Non utilizzare se la confezione è danneggiata es o No usar si el envase está dañado da o Må ikke anvendes, hvis emballagen er beskadiget fi o Ei saa käyttää, jos pakkaus on vahingoittunut nl o Inhoud van een beschadigde verpakking niet gebruiken no o Skal ikke brukes hvis forpakningen er skadet pt o Não utilizar em caso de danos na embalagem sv o Använd inte om förpackningen är skadad
⌡ (Temperature limitation)	en o Temperature limitation de o Temperaturbegrenzung fr o Limitation de la température it o Limitazione della temperatura es o Limitación de la temperatura da o Temperaturbegrænsning fi o Lämpötilaraja nl o Temperatuurlimiet no o Temperaturbegrensning pt o Limitação de temperatura sv o Temperaturbegränsning	⊢⊣ (Usable length)	en o Usable length de o Nutzlänge fr o Longueur utilisable it o Lunghezza utile es o Longitud utilizable da o Brugbar længde fi o Käyttökelpoinen pituus nl o Bruikbare lengte no o Brukslengde pt o Comprimento utilizável sv o Användbar längd

Symbol		Symbol	
☂	en o Keep dry de o Vor Nässe schützen fr o Conserver au sec it o Mantenere asciutto es o Mantener seco da o Skal holdes tor fi o Pidä kuivana nl o Droog houden no o Oppbevares tørt pt o Manter seco sv o Förvaras torr	📦	en o Contents de o Inhalt fr o Contenu it o Contenuto es o Contenido da o Indhold fi o Sisältö nl o Inhoud no o Innhold pt o Conteúdo sv o Innehåll
☀	en o Keep away from Sunlight de o Vor Sonnenlicht schützen fr o Tenir à l'écart de la lumière du soleil it o Tenere lontano dalla luce del sole es o Mantener alejado de la luz solar da o Skal holdes væk fra sollys fi o Pidä poissa auringonvalosta nl o Verwijderd houden van zonlicht no o Holdes borte fra sollys pt o Proteger da luz solar sv o Håll borta från solljus	➡	en o Temperature sensor de o Temperatursensor fr o Capteur de température it o Sensore di temperatura es o Sensor de temperatura da o Temperatursensor fi o Lämpötila-anturi nl o Temperatuursensor no o Temperatursensor pt o Sensor de temperatura sv o Temperaturgivare
MD	en • Medical Device de o Medizinprodukt fr o Dispositif médical it o Dispositivo medico es o Producto sanitario da o Medicinsk udstyr fi o Lääkinnällinen laite nl o Medisch hulpmiddel no o Medisinsk utstyr pt o Dispositivo Médico sv o Medicinteknisk enhet	UDI	en o unique Device Identifier de o Einmalige Produktkennung fr o Identifiant unique de l'appareil it o Identificatore unico del dispositivo es o Identificador único del producto da o unik udstyrsidentifikation fi o yksilöllinen laitetunniste nl o unieke apparaatidentificatie no o unik enhetsidentifikator pt o Identificador Único de Dispositivo sv o unik enhetsidentifierare
◌	en • Single sterile barrier system with protective packaging de o Einfaches Sterilbarrieresystem mit Schutzverpackung fr o Système de barrière stérile simple avec emballage de protection it o Sistema di barriera sterile singola con imballaggio protettivo es o Sistema de barrera estéril sencillo con envase protector da o Enkelt sterilt barrieresystem med beskyttende emballage fi o Yksittäinen steriili estojärjestelmä suojapakkauksella nl o Enkelvoudig steriel barrièresysteem met beschermende verpakking no o Enkelt sterilt barrieresystem med beskyttende forpakning pt o Sistema de barreira estéril individual com embalagem de proteção sv o Enkelt sterilt barriärsystem med skyddsförpackning	◯	en • Single sterile barrier system de o Einfaches Sterilbarrieresystem fr o Système de barrière stérile simple it o Sistema di barriera sterile singola es o Sistema de barrera estéril sencillo da o Enkelt sterilt barrieresystem fi o Yksittäinen steriili estojärjestelmä nl o Enkelvoudig steriel barrièresysteem no o Enkelt sterilt barrieresystem pt o Sistema de barreira estéril individual sv o Enkelt sterilt barriärsystem
🏭	en • Distributor de o Händler fr o Distributeur it o Distributore es o Distribuidor da o Distributor fi o Jälleenmyyjä nl o Distributeur no o Distributor pt o Distribuidor sv o Distributör	LATEX	en • Latex free de o Latexfrei fr o Sans latex it o Senza lattice es o Sin látex da o Latexfri fi o Lateksiton nl o Latexvrij no o Lateksfri pt o Sem látex sv o Latexfri

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$R_{\text{X ONLY}}$	en	• Medical prescription		
	de	o Verschreibungspflichtig		
	fr	o Prescription médicale		
	it	o Prescrizione medica		
	es	o Prescripción médica		
	da	o Kun på ordination		
	fi	o Lääkemääräys		
	nl	o Medisch voorschrift		
	no	o Medisinsk resept		
	pt	o Prescrição médica		
	sv	o Recept		

Caution: Please read these instructions carefully before using the product.
UDI: Information on general safety and performance requirements is publicly available at
https://ec.europa.eu
Basic UDI-DI: 4044508iConnectCBS

Part A: Product Description

A1. Device Description

The product is used for the connection of an ablation catheter to an RF generator. It is used in intra-cardiac, electrophysiological studies for the transmission of signals and stimulation/ablation impulses for intra-cardiac diagnosis and therapy of cardiac arrhythmias.

A2. Variants & Models

REF	Product name	Brief description
001-009071-1	CELSIUS – iCONNECT	Catheter cable for connecting the iCONNECT System to: a) CELSIUS® THERMOCOOL RMT Catheter b) CELSIUS® RMT Catheter
001-009073-1	MAGNOFLUSH – iCONNECT	Catheter cable for connecting the iCONNECT System to: a) MedFact MAGNOFLUSH Catheter
001-009074-1	MAGIC - iCONNECT	Catheter cable for connecting the iCONNECT System to: a) Stereotaxis MAGIC Catheter

A3. Accessories

None.

A4. Combinations with other Medical Devices

See table in chapter A2.

A5. Intended Purpose

The catheter cables are accessories for other medical devices like ablation RF generators and ablation catheters.

The function of the cables is the electrical connection between the catheters and the RF generators, including extensions and adapters or boxes.

The cables of the series are identical in design and application. They differ concerning the plugs as different catheter and RF generator combinations have to be considered.

Note: see instructions for use of external ablation devices and ablation catheters to be connected.

A6. Patient Population

The patient population of the catheter cables is connected to the intended use of the corresponding ablation catheter. Therefore, the patient population for the catheter cables is not restricted.

A7. Intended Medical Indication (= Indication)

The medical indication of the catheter cables is connected to the intended medical indication of the corresponding ablation catheter. Ablation catheters are used for the treatment of cardiac arrhythmias. Refer also to the Stereotaxis iCONNECT User Guide and catheter cable to be connected.

A8. Expected clinical benefit

The product allows the diagnosis and treatment of patients with cardiac arrhythmias in combination with an ablation catheter and RF generator as part of an electrophysiological examination, where the products functions as a connecting device.

A9. Contraindications

There are no general contraindications for the use of the catheter cables, because they have no medical capabilities themselves. Therefore, see product information of connected devices and catheters.

A10. Possible complications/side effects

n/a, complications or side effects are dependent on the used catheter and/or the generator.

A11. Warnings/Precautions

Caution: Use of the product in sterile conditions. The product may only be used in a medical treatment facility that has been specifically set up for the appropriate application and by trained staff. The product may only be used if its safe application can be guaranteed. It is the doctor's responsibility to select the medically appropriate procedure and method. The operating instructions are intended purely as general information on handling the product. The product must not be modified in any way. Warnings / general information / precautionary measures must always be observed even if a differing procedure is chosen for medical reasons. Failure to observe these can result in complications and malfunction.

The product, packaging and any accessories must be inspected for damage and malfunction before use. The product must not be used if any damage or malfunction is encountered. If the instructions for use are no longer available, you can request replacement instructions from OSYPKA AG. The instructions for use may only be disposed of after all products in the product unit have been used.

The safety regulations for electrical devices should be observed in order to avoid patient current leakage:

- Monitor the patient continuously. Keep a defibrillator available for emergencies.
- Conductive connectors and contact surfaces of applied parts may not be touched or come into contact with conductive parts or wet surfaces, including the ground.
- The electrostatic voltage between the user and the patient should be balanced out before the patient cable is touched, e.g. by touching the patient at a site far away from the electrode.
- The patient cable should not touch either the patient or other wires.
- The rated voltage for patient cables is effectively 150 V. The output set on the external ablation device should not exceed 150 W.
- The connectors of the patient cable should not be immersed in liquids.
- Patient cables and grips should not be treated with organic solvents.
- Follow the instructions for use of external ablation devices to be connected and the ablation catheter.

A12. Cleaning:

Inspection of the product for visible damage and wear:

- Damage to the product, e.g. tears, rough surfaces,
- Damage to the insulation of the product and/or the cable/connector, e.g. tears and cracks.

If there is still visible contamination on the product after cleaning/disinfection, the entire cleaning and disinfection procedure must be repeated.

Part B: General Notes and Precautions

B1. Intended Users (Use and handling)

Caution: Use of the product in sterile conditions.

The product may only be used by trained staff in a medical treatment facility that has been specifically set up for the appropriate application. The product may only be used if its safe application can be guaranteed. It is the doctor's responsibility to select the medically appropriate procedure and method. The operating instructions are intended purely as general information on handling of the product. The product must not be modified in any way.

Refer also to the Stereotaxis iCONNECT User Guide for cable handling, connection, and instructions for use.

The warnings / general instructions / recommendations are - also in the case of a medical reason - to be observed in every case! Failure to do so can lead to complications and malfunctions!

B2. Sterilisation and storage

The products are sterilised with ethylene oxide. Provided the sterilised product is stored correctly, it may be used up until expiry date (use before date) indicated on the package. Store the sterile product in its original packaging in a cool, dry place away from light at between 10°C and 25°C.

B3. Disposal

The product may be contaminated after use. After use, this product may be a potential biohazard. Handle and dispose of in accordance with medical practice and applicable local, state and federal laws and regulations. For this reason please observe your hospital's regulations regarding disposal. Any pointed or sharp objects such as needles, hypodermic needles or scalpels that were part or used with the product must be disposed of safely and separately in order to prevent injury and infection.

B4. OSYPKA AG Limited Warranty

OSYPKA AG warrants its products to be free from defects in workmanship and materials under normal use. This warranty is valid only before the expiration date indicated on the product labeling. The product shall be used only in accordance with the labeling and shall not be modified or subjected to misuse, abuse, accident or improper handling. Proper handling and approved methods of use of the product are described in the "Instructions for Use" document included with each product. OSYPKA AG disclaims all responsibility and liability for the use of its products in a manner not authorized or approved.

OSYPKA AG's liability under this warranty is limited to the replacement of its products. The foregoing warranty disclaims and is in lieu of all other warranties of merchantability or fitness for a particular purpose. OSYPKA AG disclaims all liability for incidental or consequential damages, losses, or expenses arising directly or indirectly from the use of this product, except as expressly provided by specific law.

OSYPKA AG does not assume or authorize any other person to assume any other or additional liability for loss, damage or expense in connection with this product. For further information, please refer to the OSYPKA AG General Terms and Conditions, which is available from OSYPKA AG or on the back of an OSYPKA AG invoice.

B5. Reporting of serious incidents

The user of this product is obliged to report any serious incident that has occurred in relation to this device to OSYPKA AG and the competent authority in its country.

B6. Re-use of Product

B6.1 Pre-cleaning

Rinse off surface contamination on the product with distilled or deionized water (if necessary, additionally with a soft cloth).

B6.2 Manual cleaning and disinfection

Use of a liquid cleaning agent suitable for preparing an immersion bath.

Use of a disinfectant compatible with the cleaning agent, suitable for preparing an immersion bath.
Tested with:

Cidezyme® LF/Enzol cleaning agent.

Disinfectant Cidex® OPA (Johnson & Johnson Medical Limited)

Disinfect only clean, slightly dried products.

1. Prepare a cleaning bath according to the manufacturer's instructions.
2. Place the product in the bath so that the surface is completely wetted.
3. Observe the recommended exposure time of the cleaning agent manufacturer.
4. Remove any dirt still adhering to the surface with a soft brush or a clean soft cloth.
5. Remove the product from the bath.
6. Rinse the product under running water.
7. Dry the product with compressed air.
8. Prepare a disinfection bath according to the manufacturer's instructions.
9. Place the product in the bath so that the surface is completely wetted.
10. Observe the recommended exposure time of the disinfectant manufacturer.
11. Remove the product from the bath.
12. Rinse the product with distilled or deionized water.
13. Dry the product with compressed air.

B6.3 Machine cleaning and disinfection

The washer-disinfector must have a basically tested effectiveness (e.g. CE marking according to DIN EN ISO 15883).

This cleaning and disinfecting agent should be suitable for medical products made of plastic and metal and have a pH value between 5.5 and 11.

Always follow the instructions of the detergent and disinfectant manufacturer.

Tested with:

Cleaning agent neodisher® mediclean forte (Dr. Weigert GmbH, Hamburg/Germany)

1. Place the product loosely rolled up in a rinsing basket. Make sure that the product does not touch any other instruments/instrument parts.
2. Starting a tested program with the following characteristics:
- Thermal disinfection (5-10 minutes at 90-93°C)
- Final rinse with distilled or deionized water
- Sufficient drying of the product
3. If, after the end of the programme, the product still has visible contamination, the machine cleaning/disinfection must be repeated.

B6.4 Control

Checking the product for damage and wear:

- Damage to the product, e.g. cracks, rough surfaces
- Damage to the insulation of the product and/or the cable/plug, e.g. cracks and breaks

If, after the cleaning and disinfecting process, there are still visible leakages on the product, the entire cleaning and disinfecting process must be reversed.

Do not use damaged products.

B6.5 Packaging

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Packaging of products in sterile containers (according to ISO 11607).

B6.6 Sterilisation
Sterilize only cleaned and disinfected products.
The cables are sterilized with a buffer.
The maximum sterilization temperature is 134°C.
Note: Maximum 10 resterilization cycles are permitted.
- Fractionated vacuum process with sufficient product drying
- Holding time 5 min at 134°C
- Sterilizer in accordance with applicable national standards and regulations (e.g. DIN EN 13060 or DIN EN 285)
- Sterilization process validation according to DIN EN ISO 17665

Follow the sterilization manufacturer's recommendations for loading, handling and drying times.
Limitation of reprocessing: Frequent reprocessing has an impact on this product. Please observe the above safety instructions for checking the product. In the event of damage or malfunctions, the product should not be used any more.

Part C: Directions for use

C1. Inspection of the product prior to use
The product and packaging must be inspected for damage and malfunction before use. The product must not be used if any damage or malfunction is encountered. If the instructions for use are no longer available you can request replacement instructions from OSYPKA AG. The instructions for use may only be disposed of after all products in the product unit have been used.

C2. Unpacking the product
The product must be removed from its packaging under sterile conditions and used in a sterile work area.

C3. Handling/Use of Product
The cables are used to connect ablation catheters to RF generators. The following schematic illustrates this connection:
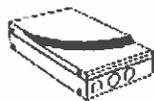
iConnect Hub   **Cable**   **Ablation Catheter**

The cables comprise of two connectors and one cable with wires. The connectors differ according to the catheters and generators to connect. These connectors are made by Redel, which are widely used in medical applications. The wires are made of copper for the connection of catheter electrodes and constantan in case of catheters using type T thermocouples (TC) as temperature sensors.