

Foliodress® cap Comfort, non-sterile

General Product Description/Intended Purpose

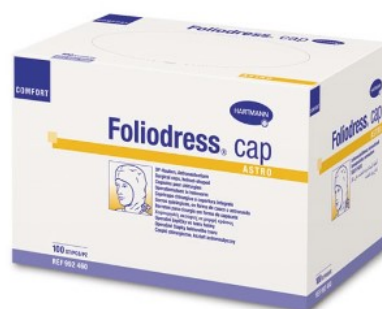
Foliodress® cap Comfort are non-sterile, single-use surgical caps for short-term use by healthcare professionals and trained lay-users in operating theatres and other clinical environments to support the reduction of particle transmission between user and patient during invasive and non-invasive procedures or other medical settings with similar requirements.

Foliodress® caps are surgical caps worn in the clinical environment. The products are available in different variants, cuts and sizes according to the performance of the caps and physique of the user.

A Foliodress® cap Comfort generally consists of a main garment body made of coloured Polypropylene spunbound or coloured viscose non-woven. Part of the Foliodress caps Comfort is equipped with a sweat-absorbing cellulose material.



The products are delivered non-sterile in carton dispenser boxes with perforation opening.



Foliodress® cap Comfort are qualified as medical devices of risk class I (non-sterile) according to EU directive MDR (Medical Device Regulation) 2017/745 and are carrying a CE mark.

The safety and effectiveness of the products Foliodress cap Comfort and Foliodress cap Universal, manufactured by Paul Hartmann AG, has been demonstrated as required by the Medical Device Regulation (EU) 2017/745 of the European Parliament.

The devices are compliant with the General Safety and Performance Requirement.

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Application/Indication

Foliodress[®] cap Comfort are non-sterile, single-use surgical caps for short-term use by healthcare professionals in operating theatres and other clinical environments to support the reduction of particle transmission between user and patient during invasive and non-invasive procedures or other medical settings with similar requirements.

Catalogue Numbers

Foliodress [®] cap Comfort	Code	Colour	Pieces/ Folding box	Folding Box/ Transport carton
Astro	992 460	auqa-green	100	6
Astro Plus	992 461	auqa-green	100	6
Apart	992 462	auqa-green	100	6
Rondo	992 463	auqa-green	100	6
Form	992 464	auqa-green	100	6
Rondo Plus	992 467	auqa-green	100	6
Form Plus	992 468	auqa-green žalia spalvos	60	6
Helmet	992 469	auqa-green	40	6
Bandana	992 477	auqa-green	100	6
Dino	992 489	aqua- green	100	6

Residual Risks, Contra-Indications and Undesirable Side Effects, Warnings

Residual Risks: Several risks were evaluated in the risk management file. No significant risk remained after design risk mitigation strategies.

Contra-Indications: not known

Undesirable Side Effects: not known

Non-sterile Device

Non-sterile device! Use in line with the intended purpose!

Single Use Device

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

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Product disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of Foliodress[®] cap Comfort products should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

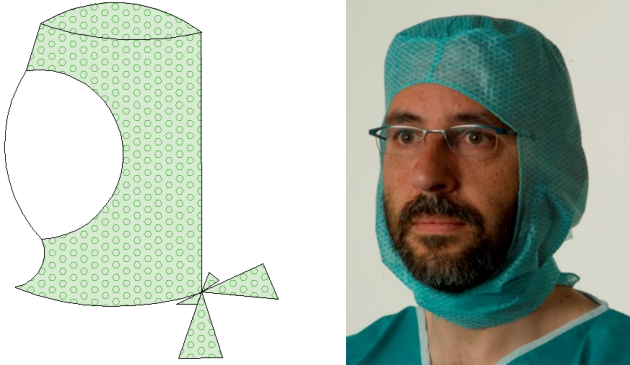
Material Characteristics

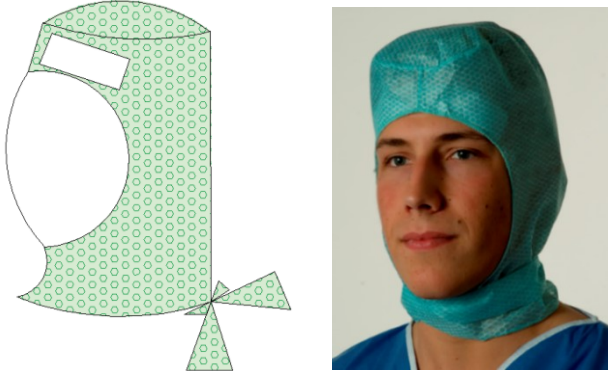
Components - Foliodress [®] cap Comfort	
Material	Viscose with binder, 25 g/m ²
Sweatband material	70% Rayon, 30% Polyester fiber, 50 g/m ²
Elastic threads	free of natural rubber latex Polyester yarn and spandex filament

Kepurėlė pagaminta iš neaustinės viskozės medžiagos, pralaidžios orui, prakaito juosta pagaminta iš polipropileno ir viskozės. Medžiaga be latekso, be ftalatų

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Product overview

Foliodress® cap Comfort – Astro	
helmet-shaped, full protection caps covering the complete head and neck area; with seamed chin ties [mm]	
<p><u>Description</u></p> <p>Length of straps 715</p> <p>Width of straps 50</p>	

Foliodress® cap Comfort – Astro Plus	
helmet-shaped, full protection caps covering the complete head and neck area; with seamed chin ties and integrated sweatband [mm]	
<p><u>Description</u></p> <p>Length of straps 715</p> <p>Width of straps 50</p>	

Foliodress® cap Comfort, non-sterile

Foliodress® cap Comfort – Apart

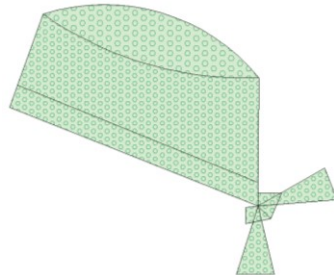
with especially designed reinforced forehead area and tie-bands, especially for longer hair [mm]

Description

Side piece

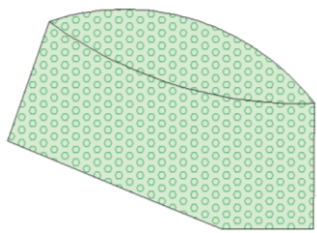
Length of straps 200

Width of straps 40



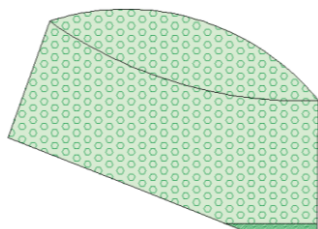
Foliodress® cap Comfort – Rondo

round shape, with double reinforced layer construction on both sides, only for wearers with short hair



Foliodress® cap Comfort – Rondo Plus

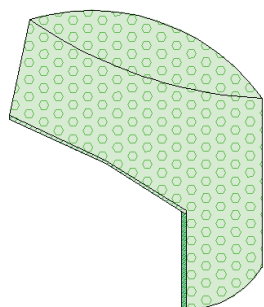
round shape, with elastic threads in the neck, especially suitable for wearers with longer hair



Foliodress® cap Comfort, non-sterile

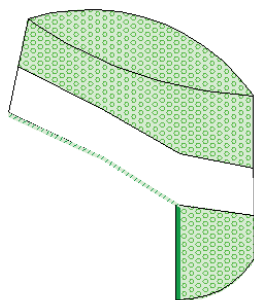
Foliodress® cap Comfort – Form

with especially designed neck part with elastic threads, especially suitable for longer hair



Foliodress® cap Comfort – Form Plus

with especially designed neck part with elastic threads, especially suitable for longer hair with sweatband around the head



Foliodress® cap Comfort – Helmet

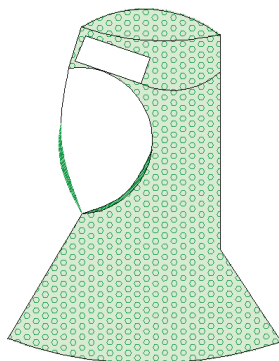
helmet-shaped, full protection caps covering the complete head, neck and shoulder area; with seamed chin ties and integrated sweatband [mm]

Description

Side piece

Length

580



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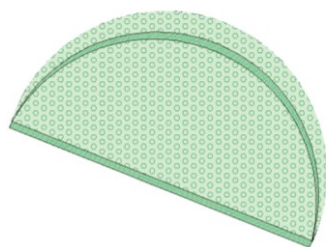
Foliodress® cap Comfort – Bandana

fancy triangle shaped shawl with ties in the neck, only for short hair



Foliodress® cap Comfort – Dino

with especially designed reinforced forehead area and tie-bands, especially for longer hair



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Product Characteristics

Components - Foliodress® cap Comfort				
Property	Test method	Unit	Requirements of EN 13795 (critical areas)	Test results
Viscose: tensile strength - dry	ISO 9073-3	N/50mm	MD*: ≥ 20	Pass
Sweatband material: tensile strength dry	ISO 9073-3	N/50mm	MD*: ≥ 20	Pass
Microbial Cleanliness	ISO 11737-1	cfu/ 100 cm ²	≤ 300	Pass
Particle release	ISO 9073-10	log 10 (lint count)	≤ 4.0	Pass

In order to underpin the beneficial effect of Foliodress® cap Comfort in the “support of the reduction of particle transmission between user and patient” and the mechanical barrier function of Foliodress caps, the manufacturer takes reference to the standard EN 13795-1:2019-06 “Surgical clothing and drapes – Requirements and test methods - Part 1: Surgical drapes and gowns” and the therein set requirements for surgical gowns of Standard Performance in non-critical areas. Here, the manufacturer considered the performance values for particle cleanliness, microbial cleanliness, tensile strength - in machine direction - as application relevant technical properties for cap fabrics.

Labelling

Lot-No. with 9-Digit Code

e.g.:



1

year

999

week
of production

XXXXXX

for internal purposes only

Date of manufacture

e.g.:



2016

year

04

month

01

day

Use-by Date

e.g.:



2021

year

04

month

01

day

Shelf Life: 5 years

Medical Device



Foliodress® cap Comfort, non-sterile

Unique Device Identifier



CE mark



Single Use Device



Producer contributes to recycling of packaging



Dispose of your waste in an appropriate manner



Recycling code for: "Corrugated fiberboard (cardboard)"

Primary packaging (dispenser) is made of corrugated paper carton



Legal manufacturer



PAUL HARTMANN AG · Paul-Hartmann-Straße 12 · 89522 HEIDENHEIM, GERMANY

Latest Date of Revision: 2022-04-06