

REGULATORY



MEDICAL DEVICE SYMBOL
ISO 15223-1:2021 (5.7.7)
Indicates the item is a medical device.



UNIQUE DEVICE IDENTIFIER
ISO 15223-1:2021 (5.7.10)
Indicates a carrier that contains unique device identifier information.



CATALOGUE NUMBER
ISO 15223-1:2021 (5.1.6)
Indicates the manufacturer's catalogue number so that the medical device can be identified.



BATCH CODE
ISO 15223-1:2021 (5.1.5)
Indicates the manufacturer's batch code so that the batch or lot can be identified.



DO NOT RE-USE
ISO 15223-1:2021 (5.4.2)
Indicates a medical device that is intended for one single use only.



INSTRUCTIONS FOR USE
ISO 15223-1:2021 (5.4.3)
Indicates the need for the user to consult the instructions for use.



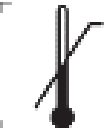
USE BY DATE
ISO 15223-1:2021 (5.1.4)
Indicates the date after which the medical device is not to be used.



PATIENT INFORMATION WEBSITE
ISO 15223-1:2021 (5.7.4)
Indicates a website where a patient can obtain additional information on the medical product.



TEMPERATURE LIMIT
ISO 15223-1:2021 (5.3.7)
Indicates the temperature limits to which the medical device can be safely exposed.



UPPER LIMIT OF TEMPERATURE
ISO 15223-1:2021 (5.3.6)
Indicates the upper limit of temperature to which the medical device can be safely exposed.



KEEP AWAY FROM SUNLIGHT
ISO 15223-1:2021 (5.3.2)
Indicates a medical device that needs protection from light sources.



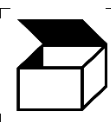
KEEP DRY
(ISO 15223-1:2021 (5.3.4)
Indicates a medical device that needs to be protected from moisture.



CAUTION
ISO 15223-1:2021 (5.4.4)
Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.



MANUFACTURER
ISO 15223-1:2021 (5.1.1)
Indicates the medical device manufacturer.



NO. OF UNITS PER PACK
ISO 7000 2794
Indicates on packaging, labelling, The quantity of product contained within the box.

EU SPECIFIC AS PER MDR 2017/745



CE MARKING

On commercial products, the letters CE mean that the manufacturer or importer affirms the good's conformity with European health, safety, and environmental protection standards

UK SPECIFIC AS PER UK MDR 2002



UK RESPONSIBLE PERSON

Indicates the authorized representative who acts on behalf of a non-UK manufacturer within the Great Britain market (England, Wales, and Scotland).



UK CONFORMITY ASSESSED

This marking is a conformity mark that indicates conformity with the applicable requirements for products sold within Great Britain

NON-REGULATORY GENERAL



GLOBAL TRADE ITEM NUMBER

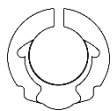
Global Trade Item Number can be used by a company to uniquely identify all of its trade items. GS1 defines trade items as products or services that are priced, ordered or invoiced at any point in the supply chain.



OSTOFORM MINI LOGO

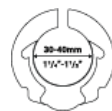
This symbol is for branding purposes only. This is used in place of the Ostoform main logo to indicate this is an Ostoform product.

OSTOFORM MOLDABLE SEAL WITH FLOWASSIST PROTECTION PRODUCT GRAPHICS



OSTOFORM SEAL

Indicates on packaging, labelling, Information for use and marketing material that adjacent information pertains to the Ostoform Seal with FLOWASSIST Protection.



SEAL SIZE

Indicates on packaging, labelling, Information for use and marketing material which size Ostoform Seal with FLOWASSIST Protection the adjacent material/text is referring to. Size will be indicated by text in the center of the Seal, along an arrow. With millimeters (mm) shown first and inches (") shown second



CORRECT ACTION

Displayed as part of or adjacent to an instructional image. Indication that the displayed image is the correct outcome or action.



INCORRECT ACTION

Displayed as part of or adjacent to an instructional image. Indication that the displayed image is the incorrect outcome or action.



CUT WITH SCISSORS

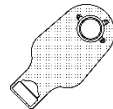
Indicates in the Information for use and marketing material when/how you should cut to accommodate the Ostoform FLOWASSIST Spout using scissors.

OSTOFORM FLOWASSIST TWO PIECE POUCHING SYSTEM PRODUCT GRAPHICS



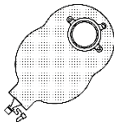
BASEPLATE

Indicates on packaging, labelling, Information for use and marketing material that adjacent information pertains to the Ostoform FLOWASSIST Flat Baseplate.



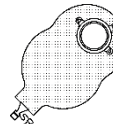
DRAINABLE POUCH

Indicates on packaging, labelling, Information for use and marketing material that adjacent information pertains to the Ostoform FLOWASSIST Drainable Pouch.



UROSTOMY POUCH

Indicates on packaging, labelling, Information for use and marketing material that adjacent information pertains to the Ostoform FLOWASSIST Urostomy Pouch.



CLOSED POUCH

Indicates on packaging, labelling, Information for use and marketing material that adjacent information pertains to the Ostoform FLOWASSIST Closed Pouch.



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TIME INDICATED

Indicates the amount of time a step or action should take to complete. The time will always be specified in writing on the left-hand side of the clock face.



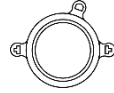
BASEPLATE SIZE

Indicates on packaging, labelling, Information for use and marketing material which size Ostoform FLOWASSIST Baseplate the adjacent material/text is referring to. Size will be indicated by text at the bottom of the Baseplate. With millimeters (mm) shown first and inches (") shown second.



CUT WITH SCISSORS

Indicates on packaging where you should cut the Ostoform FLOWASSIST Baseplate using scissors.



CLIC RING SIZE

Indicates on packaging, labelling, Information for use and marketing material which size Clic Ring the adjacent material/text is referring to. Size will be indicated by text and colour in the center of the Clic Ring.



FLAT BASEPLATE

Indicates on packaging, labelling, that this product is the Ostoform FLOWASSIST Flat Baseplate.



CONVEX BASEPLATE

Indicates on packaging, labelling, that this product is the Ostoform FLOWASSIST Convex Baseplate.