TECHNICAL DATA SHEET

ACE Stopper

Reference: **APxx/xx**

Trade Name: **ACE Stopper**

Size and Length options

	8Fr	10Fr	12Fr	14Fr
 *15 mm*	AP8/15	AP10/15		
 *30 mm*	AP8/30	AP10/30	AP12/30	AP14/30
 *60 mm*	AP8/60	AP10/60	AP12/60	AP14/60
 *100 mm*			AP12/100	AP14/100

PRODUCT DESCRIPTON:

The Medicina ACE stopper devices are small silicone stoppers that are used to seal stoma sites at various parts of the body. **They can be used for up to 30 days.**

INTENDED USE:

The ACE stopper is indicated for patients with ante-grade continence enemas, where they are required to seal the tract or maintain patency in between insertions of the enema catheter.
ACE stoppers are also indicated for stomas formed for catheter introduction into the bladder. They can also be used for any stoma of suitable size, anywhere in the body.

RAW MATERIAL:

Silicone

PACKAGING:

Primary packaging:

- Paper/PP-PE film Blister

Secondary Packaging (Pouch):

- ACE Stopper
- ACE Stopper dressing
- Instructions for Use

Tertiary Packaging (Box):

- sealed white cardboard box containing the secondary pack

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The stoppers are not sold alone they are sold as part of a procedure pack.
Reference Features: Unit

Code	FR	Length mm	ACE Stopper	Code	FR	Length mm	ACE Stopper
AP8/15	8	15	1	AP12/30	12	30	1
AP8/30	8	30	1	AP12/60	12	60	1
AP8/60	8	60	1	AP12/100	12	100	1
AP10/15	10	15	1	AP14/30	14	30	1
AP10/30	10	30	1	AP14/60	14	60	1
AP10/60	10	60	1	AP14/100	14	100	1

STERILISATION:
EtO Sterilisation of the ACE stopper is undertaken in accordance with the requirements of the current regulations. The device should not be re-sterilised.

SHELF LIFE:
Shelf life 3 years from sterilisation

USAGE:
Single patient use device

CLEANING:
The ACE Stopper can be washed with warm soapy water.

STORAGE:
Standard storage procedures and conditions.

DISPOSAL:
The user must follow the legal regulations regarding disposal of hospital waste.

MANUFACTURER:
Medicina Ltd
Units 2-4 Rivington View Business Park, Station Road, Blackrod, BL6 5BN

EC REPRESENTATIVE:
HMC Premedical S.p.A.
Via Bosco 1/3, 41037, Mirandola (MO) – Italy

NOTIFIED BODY:
SGS Belgium NV – CE1639
Certificate Number: GB19/964955

CLASSIFICATION:
Class IIb device with sterility

CONFORMITY ASSESSMENT ROUTE:
Directive 93/42/EEC on Medical devices, Annex II

REVISION HISTORY:			
Revision No:	**Date:**	**Summary of changes**	**Issued by:**
01	04/05/2020	First issue with CE1639	Joanne Schmidt
02	17/02/2021	Addition of EC representative	Joanne Schmidt