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3. Product Description

3.1. General Description

1) Product Name : Gutta Percha Points

Absorbent Paper Points

3.2. Intended Use

1) Gutta Percha Points : To fill the root canal of a tooth.

2) Absorbent Paper Points : For use during endodontic therapy to dry the canal.

3.3 General Description

3.3.1 Gutta Percha Points

Pearldent GUTTA PERCHA is a device made from coagulated sap of certain tropical trees intended to fill the root canal of a tooth.

The GUTTA PERCHA is inserted into the root canal,

Hand rolled tapered shape gutta percha points contain;

DESCRIPTION	SPECIFICATION	LOCATION
GUTTA PERCHA	PD-GP-001	QA
ZINC OXIDE		
BARIUM SULFATE		
COLORING AGENT		

The GUTTA PERCHA POINT is manufactured in accordance with ISO 6877 which are various in size and package.

The GUTTA PERCHA POINT is to be stored in cool area and not to be autoclave or heat sterile.

It's not known to cause significant health problems.

MDD product category ; Class 11a

GUTTA PERHCHA POINT is being used as a filling material (permanent use) of the cleaned root canals of tooth.

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3.3.2 Absorbent Paper Points

Pearldent ABSORBENT PAPER POINT is a device made from highly absorbent natural paper intended to clean the root canal of a tooth by insertion and removal.

Hand rolled tapered shape paper point is manufactured according to ISO various in size and package.

Sterile method ; Irradiated gamma ray

Specified dose- 25 KGy

The ABSORBENT PAPER POINT is to be stored not to be autoclave and supplied in sterilized condition. It is not known to cause significant health problems.

MDD product category ; Class 11a(RULE 6, ANNEX IX)

ABSORBENT PAPER POINT is being used to dry the canal.

3.4 Product Specification and Type

3.4.1 Gutta Percha Points

1) Standard Size

(1) Size

SIZE	DIAMETERS	COLOR	SIZE	DIAMETERS	COLOR
15	0.15	WHITE	60	0.60	BLUE
20	0.20	YELLOW	70	0.70	GREEN
25	0.25	RED	80	0.80	BLACK
30	0.30	BLUE	90	0.90	WHITE
35	0.35	GREEN	100	1.00	YELLOW
40	0.40	BLACK	110	1.10	RED
45	0.45	WHITE	120	1.20	BLUE
50	0.50	YELLOW	130	1.30	GREEN
55	0.55	RED	140	1.40	BLACK

* Diameter means the diameter of Product's tip.

* All product length is 28±2mm.

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(2) Type

- * PINK GUTTA PERCHA POINTS
- * COLOR GUTTA PERCHA POINTS
- * COLOR CODED GUTTA PERCHA POINTS

2) REGULAR SIZE

(1) Size

XF, FF, MF, F, FM, M, ML, L, XL

ALL PRODUCT LENGTH IS 28±2mm.

(2) Product Type

- * PINK GUTTA PERCHA POINTS
- * PURPLE GUTTA PERCHA POINTS

3) Japanese Size

(1) Size

SIZE	LENGTH±1mm	SIZE	LENGTH±1mm
FS(Fine-Large)	17	M(Medium)	21
FM(Fine-Medium)	21	L(Large)	26
FL(Fine-Large)	25	LM(Large-Medium)	21
S(small)	15	XL(Extra-Large)	27

(2) Type

- * PINK GUTTA PERCHA POINTS
- * PURPLE GUTTA PERCHA POINTS

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3.4.2 Paper Points

1) Standard Size

(1) Size

SIZE	DIAMETERS	COLOR	SIZE	DIAMETERS	COLOR
15	0.15	WHITE	60	0.60	BLUE
20	0.20	YELLOW	70	0.70	GREEN
25	0.25	RED	80	0.80	BLACK
30	0.30	BLUE	90	0.90	WHITE
35	0.35	GREEN	100	1.00	YELLOW
40	0.40	BLACK	110	1.10	RED
45	0.45	WHITE	120	1.20	BLUE
50	0.50	YELLOW	130	1.30	GREEN
55	0.55	RED	140	1.40	BLACK

* Diameter means the diameter of Product's Tip.

* All product length is 28±2mm.

(2) Product Type

* PAPER POINTS

* COLOR CODED PAPER POINTS

3.5 Classification

Product Name	Gutta Percha Points	Absorbent Paper Points
Class	IIa, Rule8	IIa, Rule6
Refer to Attachment	CHECKLIST OF CLASSIFICATION CRITERIA OF MEDICAL DEVICE DIRECTIVE 93/42/EEC (DOC.NO. : PD01-CLS-01)	CHECKLIST OF CLASSIFICATION CRITERIA OF MEDICAL DEVICE DIRECTIVE 93/42/EEC (DOC.NO. : PD01-CLS-02)