



Healing of Human Extraction Sockets After the Use of Foundation™

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ABSTRACT

Objective: To assess the healing of human extraction sockets following the grafting of Foundation™, a collagen-based socket preservation material (J. Morita USA; manufactured by Olympus-Terumo Biomaterials, Tokyo, Japan). Methods: Eighteen subjects (10 males and 8 females) who were scheduled for extraction (10 molars, 5 premolars and 3 incisors) participated in this study. Immediately after the tooth extraction under local anesthesia, the Foundation graft was inserted into the extraction sockets and sutured in place. Biopsies from the healed extraction sites were done using trephine osteotomy at 8 weeks after grafting at the time of implant placement.

Acid-etched Sterngold Implamed root-form dental implants (3.75 to 5.0mm in diameter, 8.5 to 13.0mm in length) were inserted into the osteotomy sites and allowed to heal for 2 to 3 months before final restoration with porcelain-fused-to-metal crowns. The cylindrical bone segments obtained by biopsy were scanned with a high-resolution micro-computed tomography (μ CT, vivaCT 40, Scanco Medical) to determine the value of the total volume of the contoured callus area (TV), the bone volume (BV) within contoured TV, the BV/TV ratio, and the average density of the bone compared to the hydroxyapatite (HA) calibration standard. The specimens were decalcified using 10% EDTA, embedded, sectioned, and stained with hematoxylin and eosin.

New bone formation was identified using polarized microscopy. The expression of osteoblast activity during bone healing was evaluated by the immunohistochemical method for BMP-2 and PDGF-B.

Results: Histology results from the sections showed very active stages of woven bone formation. A majority (86%) of the bone biopsy specimens were comprised of newly formed woven bone (range 72-97%). BMP-2 and PDGF-B positive osteoblasts were observed lining the edge of the newly formed woven bone, indicating an active process of bone formation. μ CT showed a mean BV/TV of 52%, and a mean mineral density of 865mm HA/ccm, signifying that the extraction sites were still undergoing a healing process towards the formation of mature lamellar bone.

BACKGROUND

For the successful placement of dental implants, and to fulfill functional and esthetic demand, a sufficient amount of alveolar ridge is required. Following the tooth extraction, the healing process usually occurs with substantial reduction of the original height and width of the alveolar bone (Amler 1969; Mccall and Rosenfeld 1991; Araujo and Lindhe 2005). To preserve the alveolar ridge, many studies have been conducted using various graft materials including autogenous, allogeneous, xenogenic and alloplastic bone graft (Artzi Tal and Dayan 2000; Becker et al 1998; Carmagnola Adriaens and Berglundh 2003; Dies et al 1998; Froum et al 2002; Guarnieri et al 2004; Iasella et al 2003; Sandor et al 2003). Controversy still exists, however, on what constitutes ideal socket preservation material.

Foundation is a collagen-based bone filling augmentation material for use in the filling of extraction sockets. It consists of fibrillar that provides scaffolding for cell attachment and promotes the faster growth of bone (Turchi 2007). Today, there is very limited information focusing on detailed characterization of bone healing in human extraction sockets. Therefore, our study was to assess the quality of newly formed bone in human extraction sockets after the use of Foundation.

MATERIALS AND METHODS

Study Population

18 subjects (10 males and 8 females), participated in this study.

Inclusion Criteria

- 18 years of age or older (in good physical and mental health). One to two teeth in maxillary or mandibular dentitions in need of extraction due to caries related infections, root fracture, trauma and failed root canal therapy. Proximal and distal teeth must be present and free from periodontal diseases.
- Be able to sign an informed consent.

Exclusion Criteria

- Allergic to products containing bovine collagen.
- Significant buccal and palatal wall bone loss (more than 50%).
- Significant bone resorption of adjacent teeth due to periodontal diseases.
- Smoking.
- Immune compromised individuals.
- Medical condition which requires premedication prior to dental procedures/visits.
- Subjects unable or unwilling to sign the informed consent form.
- Pregnant or nursing women.
- Participation in any other clinical study or test panel within 2 weeks prior to enrollment into this study.
- Patients who do not read or speak English.

Timeline of the Study

Day 0	2-month	5-month	8-month	11-month
Exo+ Foundation	Implant	Restorative	Follow up 1	Follow up 2

Socket Preservation Material

Foundation



Foundation is a biodegradable bone augmentation material made from bovine atelo-collagen. Foundation is placed into the socket immediately after tooth extraction. It is shaped in bullet form for easy placement and is available in both small (S) and medium (M) sizes. Since it is a

biodegradable material, there is no need to remove it and no membrane is required.

Conclusion

Foundation, an atelo-collagen, is biocompatible and promotes bone growth after tooth extraction. It appears to be a suitable grafting material for socket preservation prior to implant placement.

SUBJECT PROCEDURES

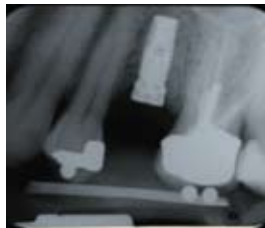
Pre-op for tooth #13



Post ext. #13, Foundation placed



2 months post ext. #13



5 months post ext. #13



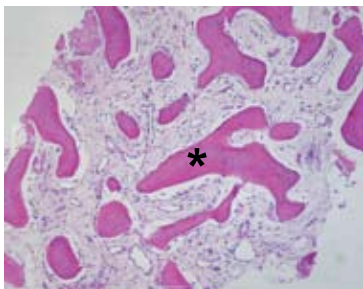
SAMPLES PROCESSING

3D μ CT images of the bone biopsy

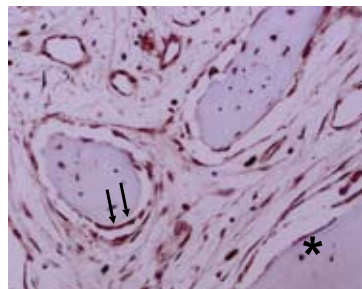


Subject ID	Tooth #	Gender	TV (mm ³)	BV (mm ³)	BV/TV	Density (mm HA/ccm)
1	4	F	25.584	10.386	0.406	742.619
2	7	F	14.575	1.92	0.132	653.099
3	8	M	18.676	9.655	0.517	809.941
4	13	M	14.478	6.857	0.474	770.421
5	19	F	59.956	30.853	0.515	944.803
6	19	M	78.199	46.882	0.599	919.185
7	19	M	76.63	46.942	0.613	918.966
8	30	F	87.288	50.04	0.573	914.818
9	19	F	68.326	29.396	0.43	808.995
10	19	F	57.307	24.855	0.43	843.129
11	14	M	107.31	50.98	0.475	895.822
12	12	F	107.39	67.83	0.63	950.335
13	30	M	96.18	52.36	0.544	868.238
14	28	M	24.284	12.61	0.52	840.508
15	13	M	34.99	3.35	0.096	664.089
16	30	M	25.88	15.02	0.58	843.93
17	13	F	73.894	30.732	0.416	915.32

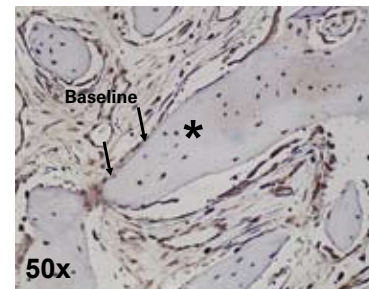
H&E (50x)



BMP-2 (200x)



PDGF-B (200x)



Immunohistochemistry: To histologically evaluate the presence of active osteoblasts during the bone healing process, an anti-BMP-2 antibody (Santa Cruz Biotech, Inc. USA) and anti-PDGF-B antibody (Santa Cruz Biotech, Inc. USA) were used.



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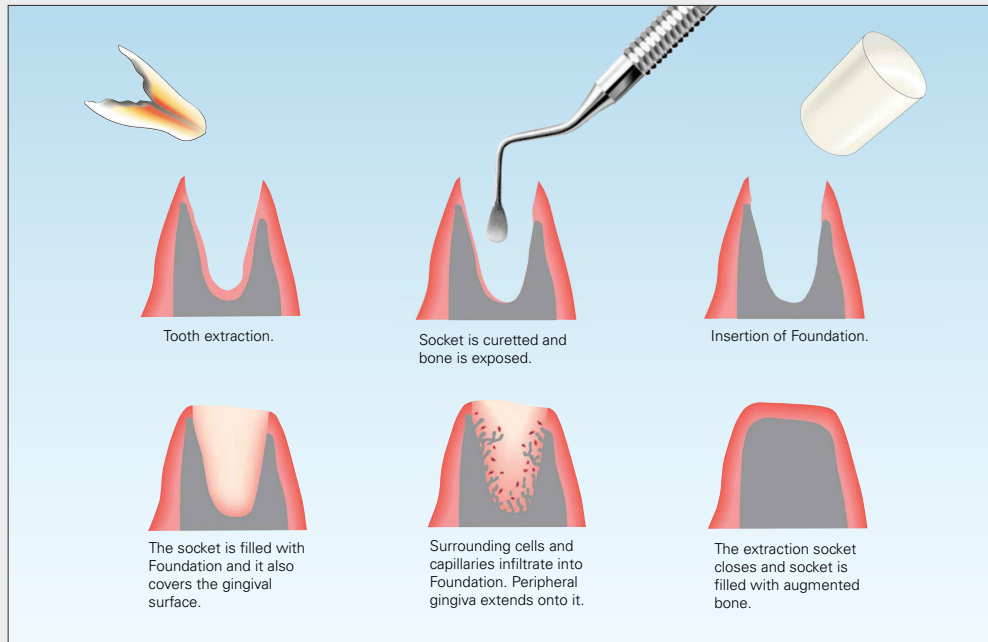
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Easy Placement, Effective Results



Foundation is composed of atelo-collagen which has been cross-linked by heat treatment in order to achieve biocompatibility. The product is provided in a bullet shape for easy placement into the extraction socket. It consists of fibrillar and heat-denatured atelo-collagen. Fibrillar atelo-collagen provides scaffolding for surrounding cells and the heat-denatured atelo-collagen stimulates infiltration of the cells into the product. Contents are sterile and non-pyrogenic.

Histology, University of Rochester, Eastman Institute for Oral Health Research

Biopsies from the healed extraction sites were taken using trephine biopsy osteotomy at 8 weeks after the placement of Foundation. The cylindrical bone segments obtained were scanned with high resolution micro-computed tomography to determine bone volume and density. The specimens were decalcified using 10% EDTA, embedded, sectioned, and stained with hematoxylin and eosin. New bone formation was identified using polarized microscopy. The biopsy taken at 8 weeks post Foundation placement (Fig. 1), shows newly formed woven bone (arrows) and newly formed woven bone with osteoblasts and ongoing bone formation (A). Fig. 2 shows higher magnification of Section A, (from Fig. 1) and also active osteoblasts are observed lining the edge of newly formed woven bone (arrows). Osteocytes are seen embedded in the newly formed woven bone (asterisks). Fig. 3 shows developing blood vessels near the newly formed woven bone (arrow).

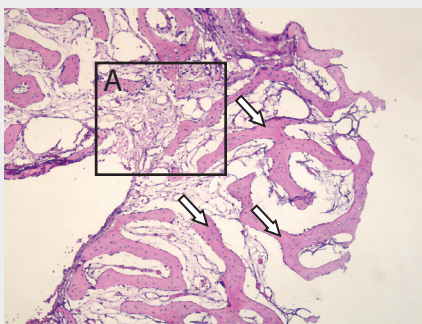


Fig. 1

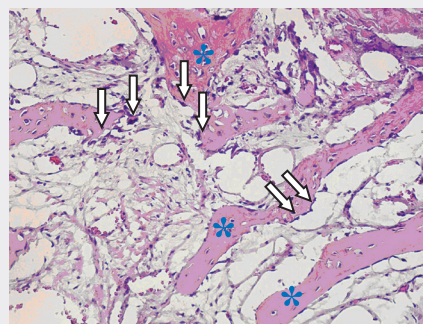


Fig. 2

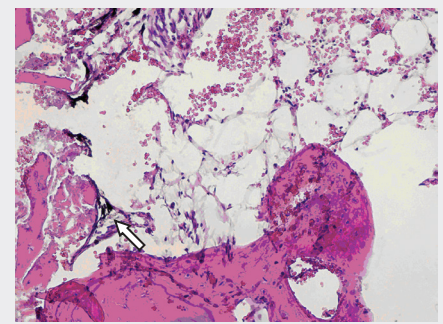
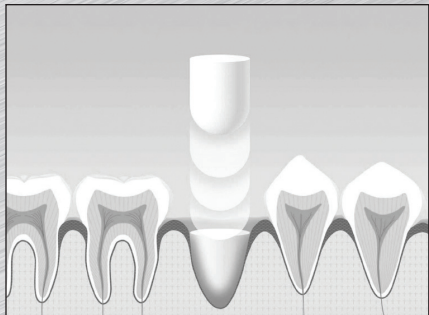


Fig. 3

Stimulates New Bone Growth



Foundation is a collagen-based, bone filling augmentation material for use after teeth extractions. It is not a bone substitute, but rather stimulates new bone growth. It has been used clinically in Japan since 1998 and has been available in North America since 2006.

Immediately following an extraction, Foundation is placed into the socket. It is shaped in "bullet" form for easy placement and is available in both small and medium sizes. Once inserted, the surrounding cells and capillaries infiltrate Foundation. As the extraction socket heals, it is filled with new augmented bone. There is no need to remove it and no membrane is required.

Foundation is helpful in maintaining bone after any permanent extraction. It is also ideal for pre-implant augmentation, as it will stimulate the bone to fill in allowing implants to be placed sooner, in some cases as early as 8 weeks. It is also recommended for third molar extraction sockets to ensure good "bony" support on the distal of the second molar.

Below is a clinical case demonstrating excellent bone growth in just 8 weeks. Case courtesy of Dr. Arthur J. Greenspoon, La Dentisterie Descelle, Montréal, QC.



Post-extraction



8 weeks post-extraction

Features

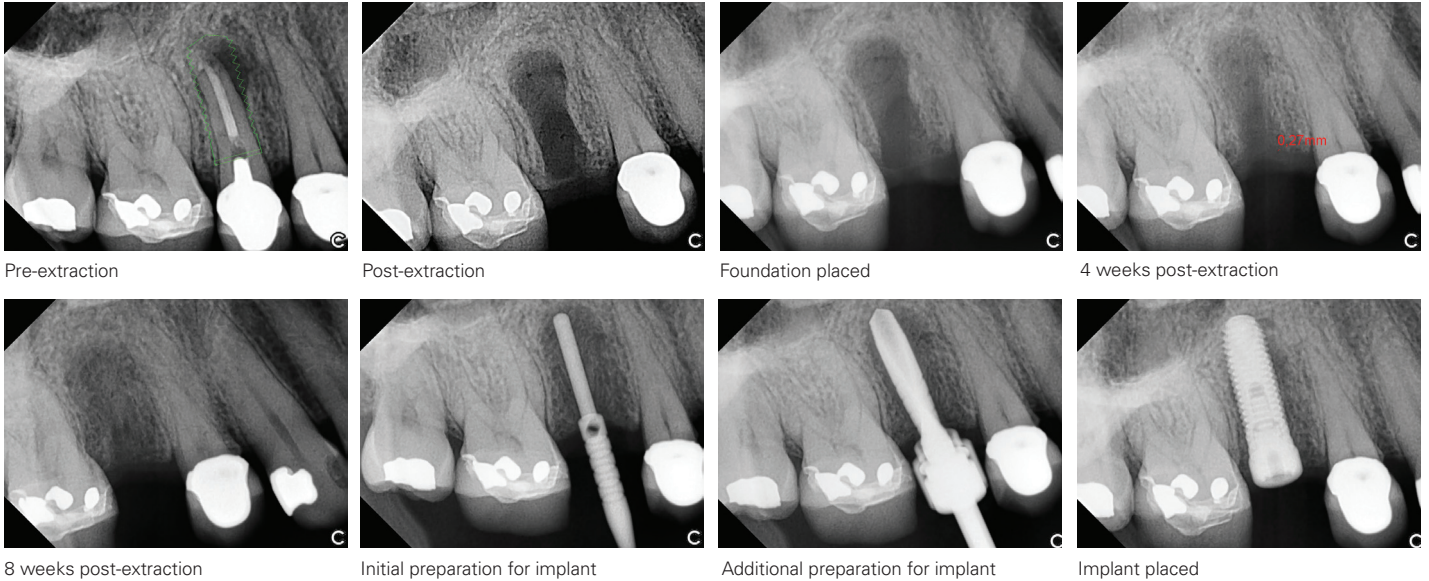
- Collagen-based, bone filling augmentation material
- Promotes bone growth after tooth extraction allowing implants to be placed as early as 8 weeks*
- Helpful in maintaining bone following permanent tooth extraction
- Bullet shaped for easy placement in extraction sockets
- Available in 2 sizes, small and medium
- Can be trimmed or shaped for a better fit
- Independent studies, including University of Rochester, Eastman Institute for Oral Health Research, available upon request



▶ **Demonstration Video & FREE CE Online at:**
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Examples of Clinical Applications

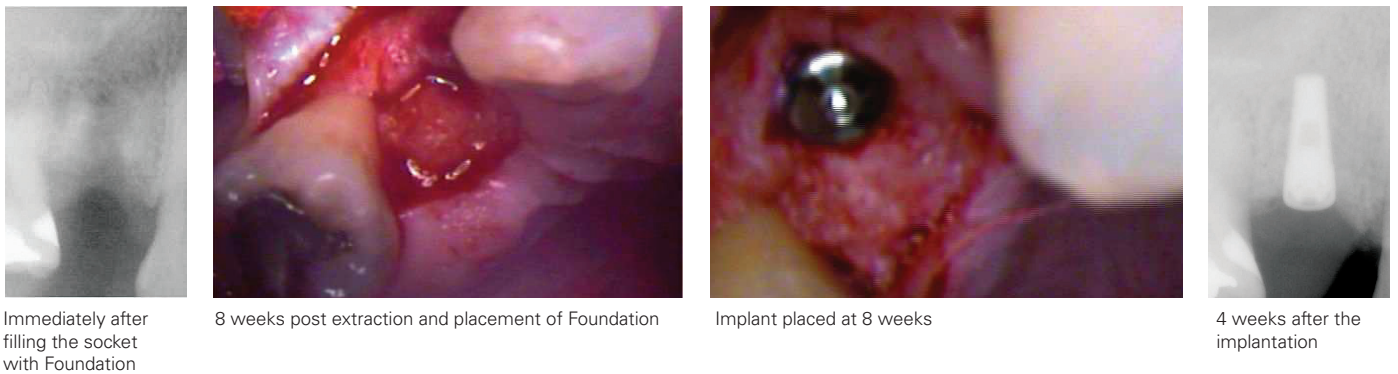
Case 1: 48 year-old female patient. Extraction was performed due to a fracture.



Courtesy: Dr. Arthur J. Greenspoon, La Dentisterie Descelle, Montréal, QC

Case 2: Extraction of a premolar due to fracture in a 31-year-old male

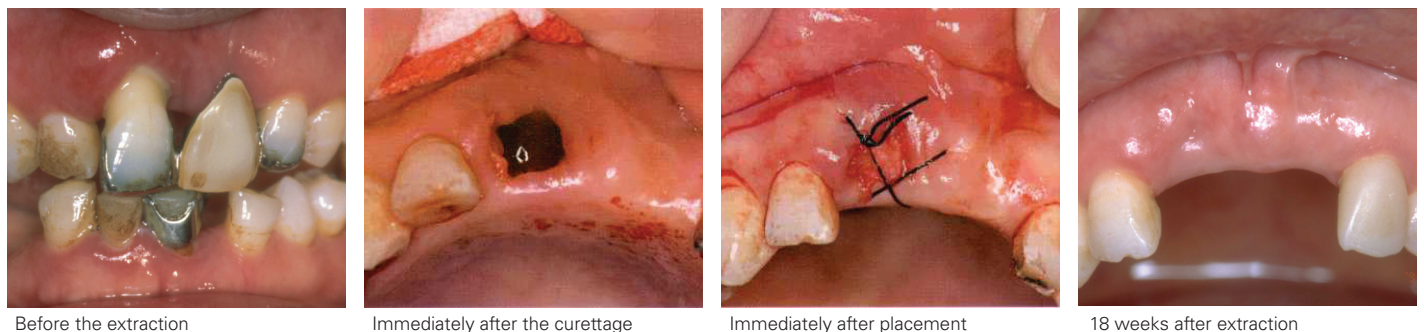
This case shows a single tooth implant that was placed after extraction due to fracture. The root of the premolar was extracted and the socket was filled with an S size Foundation. An x-ray was taken immediately after filling the socket with Foundation. 8 weeks post-op, there is horizontal bone augmentation in the socket. At this point, the bone augmented by Foundation was ready to be prepared and an implant was placed. 4 weeks post-implantation (12 weeks post-Foundation placement), the bone surrounding the abutment was filled in and the implant was firm.



Courtesy: Matsumi Dental Office, Japan

Case 3: Extraction of tooth #8 due to severe periodontal defect in a 65-year-old female

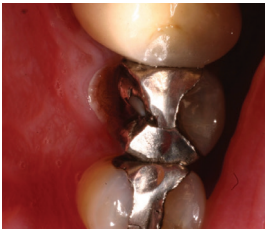
This case shows the extraction of tooth #8 due to advanced periodontal disease. #9 is a pontic. The tooth had severe gingival recession and the pus discharge confirmed an infection was present. The extraction was performed after controlling the infection with an antibiotic regimen. After the extraction, unhealthy granulation tissue in the socket was curetted. The resorption of the labial bone reached the root apex. An S size Foundation was used and the gingiva was sutured to secure it. At 18 weeks post-op, it is clearly shown that Foundation augmented the alveolar ridge and created a very good esthetic result.



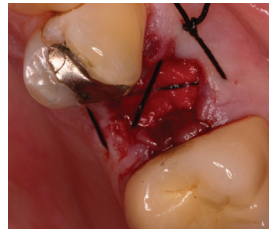
Courtesy: Kodama Dental Clinic, Japan

Case 4: Tooth extraction of #13 due to subosseous fracture of the lingual cusp

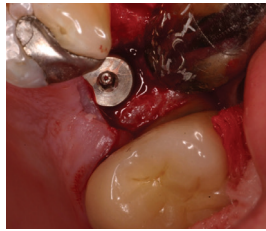
Tooth #13 was deemed "hopeless" and was extracted. Foundation was inserted and a passive suture was placed. 8 weeks following extraction, a radiograph confirmed there was sufficient bone to place the implant into a stable base. At 5 months following extraction, the permanent crown was seated.



Pre-op for tooth #13



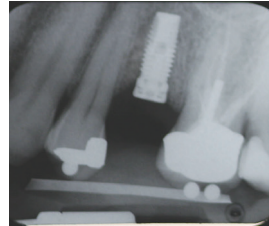
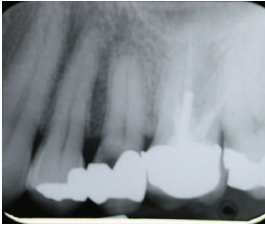
Post extraction #13, Foundation placed



8 weeks post extraction #13



5 months post extraction #13



Courtesy: University of Rochester, Eastman Institute for Oral Health

Case 5: Extraction of tooth #12 due to gross caries

The extraction of tooth #12 was necessary due to the extensive decay. The tooth was not restorable. After the root tip was extracted, the socket was thoroughly curetted to expose bone and ensure adequate blood in the socket. Foundation was placed in the socket and the healing process began. At 4 weeks the soft tissue had healed nicely. At 12 weeks an x-ray was taken which revealed adequate bone growth in the socket to place the implant. A panoramic x-ray was taken to demonstrate successful implant placement.



Prior to extraction



Removal of root tip



Curetting the socket



Foundation placed into the socket



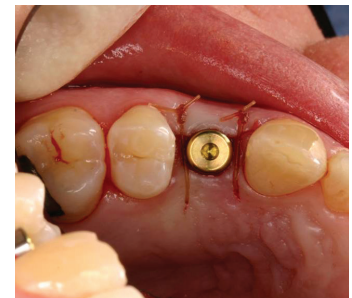
Foundation in place



4 weeks post-extraction



Placing the implant



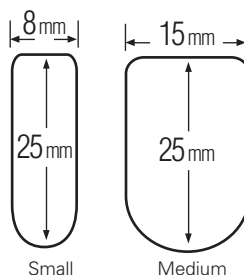
12 weeks - implant placed

Courtesy: Dr. Edward Marcus, Yardley, PA

Ordering Information

All units in each box of Foundation are individually packaged in a sterile container.

- Foundation, size small (10 units) 27-500-100
- Foundation, size medium (5 units) 27-500-200
- Foundation, assortment pack (6 units) 27-500-150
- (3 each small & medium)



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